

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	
LITIGATION)	MDL NO. 1456
)	
)	CIVIL ACTION NO. 01-12257-PBS
THIS DOCUMENT RELATES TO:)	
)	
<i>State of Nevada v. American</i>)	
<i>Home Products Corp., et al.,</i>)	
Civil Action No. 02-12086-PBS)	
and)	
<i>State of Montana v. Abbott</i>)	
<i>Labs, Inc., et al.,</i>)	
Civil Action No. 02-12084-PBS)	

MEMORANDUM AND ORDER

June 10, 2004

Saris, U.S.D.J.

I. INTRODUCTION

The States of Montana and Nevada allege that pharmaceutical manufacturers fraudulently overstate the published "average wholesale prices" ("AWP's") of many of their prescription drugs to the detriment of the States, which reimburse providers based on AWP's, and their citizens, who make co-payments based on AWP's either as part of Medicare or under third-party health insurance contracts. The States seek to recover for these AWP claims on their own behalf and acting as *parens patriae* on behalf of their citizens.

The States also allege that the Defendants reported false prices to the federal government in violation of a federal

statute requiring manufacturers to pay rebates to the states on the basis of their "Best Prices," 42 U.S.C. § 1396r-8 (the "Rebate Statute"), and in violation of each manufacturer's rebate agreement into which they entered pursuant to that statute.¹

Defendants move to dismiss on the grounds that: (1) the Plaintiffs' state claims of fraud are pre-empted; (2) the Plaintiffs' claims do not survive under Fed. R. Civ. P. 9(b); and (3) the Plaintiffs fail to state claims under the state statutes.

This case raises the novel issue of whether the federal Medicaid Rebate Statute pre-empts state law fraud claims brought by the state attorneys general, where those claims are based on pharmaceutical manufacturers' fraudulent reporting of Best Prices to the federal government. The United States Department of Justice, on behalf of the Secretary of Health and Human Services (the "Secretary") and at the request of the Court, submitted an amicus curiae brief (the "U.S. Brief") arguing that such Best Price claims are not pre-empted because they neither frustrate the administration of the rebate program nor raise the fraud-on-the agency concerns present in Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001).

The Commonwealth of Massachusetts also submitted an amicus

¹ Montana brings Best Price claims under its Deceptive Trade Practices Statute (Count II); Medicaid Fraud Statute (Count III); and False Claims Act (Count IV). Nevada brings Best Price claims under its Deceptive Trade Practices Statute (Count III); state RICO statute (Count IV); and Medicaid Fraud Statute (Count IV).

curiae brief, discussing multiple, ongoing, joint federal-state efforts to enforce the rebate program.

For the reasons given below, the motions to dismiss are **ALLOWED IN PART** and **DENIED IN PART**. Among other things, the Court holds that the Rebate Statute does not preempt state fraud actions, but dismisses most Best Price claims pursuant to Fed. R. Civ. P. 9(b) and state law.

II. BACKGROUND

The Court assumes close familiarity with the discussion of the alleged AWP scheme in its prior opinions, which set forth the factual background of the allegations as well as the appropriate legal standards. See, e.g., In re Pharm. Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172 (D. Mass. May 13, 2003) (Saris, J.) ("Pharm. I"); In re Pharm. Indus. Average Wholesale Price Litig., 309 F. Supp. 2d 165 (D. Mass. Jan. 9, 2004) (Saris, J.) ("Pharm. II"); In re Pharm. Indus. Average Wholesale Price Litig., 307 F. Supp. 2d 196 (D. Mass. February 24, 2004) (Saris, J.) ("Pharm. III").

The Court has not previously addressed the Best Price claims, so the Court shall set forth a brief background, taking the allegations of the Complaints as true except where otherwise noted.

According to the Secretary, although the Medicaid Act does not require states to cover prescription drugs, 42 U.S.C. §

1396d(a)(12), at least 44 states and the District of Columbia currently provide prescription drug coverage for categorically needy individuals, and 32 states and the District of Columbia provide such coverage for medically needy individuals. Drugs purchased by Medicaid recipients account for roughly ten percent of all prescription drugs purchased in the United States.

In 1990, Congress passed the Omnibus Budget Reconciliation Act of 1990, which created the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8. This cost-saving statute, passed "[i]n response to increasing Medicaid expenditures for prescription drugs, . . . requires drug companies to pay rebates to states on their Medicaid purchases." Pharm. Research & Mfrs. Of Am. v. Walsh, 123 S.Ct. 1855, 1861 (2003).

The new program had two basic parts. First, it imposed a general requirement that, in order to qualify for Medicaid payments, drug companies must enter into agreements either with the Secretary [of Health and Human Services] or, if authorized by the Secretary, with individual states, to provide rebates on their Medicaid sales of outpatient prescription drugs. The rebate on a "single source drug" or an "innovator multiple source drug" is the difference between the manufacturer's average price and its "Best Price," or 15.1% of the average manufacturer price, whichever is greater. 42 U.S.C. §§ 1396r-8(c)(1), (2). The rebate for other drugs is 11.1% of the average manufacturer price. See § 1396r-8(c)(3).

Second, once a drug manufacturer enters into a rebate agreement, the law requires the State to provide coverage for that drug under its plan unless the State complies with one of the exclusion or restriction provisions in the Medicaid Act. See § 1396r-8(d).

Id. at 1862.

Several aspects of the Statute are relevant to this case. First, the Statute provides an express and lengthy definition of "Best Price." After excluding the prices given to certain drug purchasers from the definition and including others explicitly, the Statute states:

the term "Best Price" -
(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);
(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and
(III) shall not take into account prices that are merely nominal in amount.

§ 1396r-8(c)(1)(C)(ii).

Second, the Statute establishes the Secretary as a go-between, collecting data from states and manufacturers to enable manufacturers to pay rebates directly to the states. The manufacturers are required to report their Best Prices and Average Manufacturer Prices ("AMP's") for drugs to the Secretary, who is required to keep the information confidential. §§ 1396r-8(b)(3)(A), (D). The Secretary then processes this information according to the formulae contained in the Statute and in the rebate agreements and reports to each state a Unit Rebate Amount ("URA"), which is "the amount calculated by the Health Care Financing Administration to which the Medicaid utilization information may be applied by states in invoicing the

Manufacturer for the rebate payment due.”² Model Rebate Agreement at I(dd) (Ex. 2 to Def. Resp. to U.S. Brief). See also § 1396r-8(b)(1)(A). States are also required to keep information disclosed by the manufacturers confidential. § 1396r-8(b)(3)(D). The states in turn are required to report to the Secretary and to the manufacturers “information on the total number of units of each dosage strength and package size of each covered outpatient drug . . . for which payment was made under the plan during the period.” § 1396r-8(b)(2). As for invoicing, the Rebate Agreements specify that the manufacturers have ultimate responsibility for the calculation:

A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

(Model Rebate Agreement at I(n).)

While the Secretary provides supplemental guidance to manufacturers regarding their Best Price obligations through program releases and training guides, the Secretary makes no determination as to what a “Best Price” is and does not negotiate with manufacturers. Rather, the manufacturers report the data and computer programs run the calculations based on formulae

² The Secretary notes that states are provided with URA’s, not the AMP’s or Best Prices, as it determined administratively that this was the best balance “for purposes of the ordinary administration of the rebate program in compliance with the statute.” (U.S. Brief at 15.)

established in the Statute and the rebate agreements.

The federal government does have some financial interest in the program. The Statute provides that amounts received by the states under the "Best Prices" program "shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of" calculating the federal contribution to state Medicaid expenditures. § 1396r-8(b)(1)(B).

Third, the Statute gives the Secretary enforcement powers. The Secretary is entitled to survey and audit manufacturers, and may impose penalties for providing late or false information. § 1396r-8(b)(3)(B). Three enforcement provisions are particularly relevant to this litigation. The first, contained in § 1396r-8(b)(3)(B), states:

The Secretary may impose a civil penalty in an amount not to exceed \$100,000 on a wholesaler, manufacturer, or direct seller, if [such entity] refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information.

The second, contained in § 1396r-8(b)(3)(C)(ii), which is entitled "Penalties . . . False information," states:

Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law.

Finally, § 1396r-8(b)(3)(C)(i) states that for any manufacturer

that fails to provide its information, "the amount of the penalty shall be increased by \$10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury."

Fourth, the statute provides states with flexibility. The Secretary has authorized at least twenty states to enter into supplemental drug rebate agreements. States are also permitted to establish prior authorization programs, § 1396r-8(d)(1)(A), to create drug formularies, § 1396r-8(d)(1)(B)(iv), to exclude certain types of drugs from the program, § 1396r-8(d)(2), to impose limitations on the minimum or maximum quantities per prescriptions "if such limitations are necessary to discourage waste, and [to] address instances of fraud or abuse by individuals in any manner authorized under this chapter." § 1396r-8(d)(6). Congress requires the states to establish oversight programs and Medicaid fraud control units for the Medicaid program generally. 42 U.S.C. §§ 1396a(a)(30), (37), (61); § 1396b(g).

These are the first actions brought by states alleging they have been harmed by fraudulent Best Price reporting.

III. DISCUSSION

A. Federal Preemption of Best Prices Claims

Defendants argue that the States' claims that the Defendants reported fraudulent Best Prices to the Secretary and so underpaid

the States are preempted by the Rebate Statute. Defendants admit that these claims are not expressly preempted, but argue that they are preempted under implied conflict preemption.

This Court addressed the issue of federal preemption of state fraud claims in Pharm. I, 263 F. Supp. 2d at 186-92 (addressing implied conflict preemption and ERISA preemption) and Pharm. II, 309 F. Supp. 2d at 171-77 (addressing ERISA preemption). Pharm I. involved the question of whether Plaintiffs' claims that Defendants fraudulently inflated AWP's, a term used in the federal Medicare statute, in violation of state consumer protection statutes were preempted by the Medicare Act. This Court held that the claims were not preempted, for there was no actual conflict with the operation of the federal program. Pharm. I, 263 F. Supp. 2d at 188.

"The guiding principle throughout the preemption analysis is Congressional intent." Pharm. I, 263 F. Supp. 2d at 187. In the analysis applicable here, "the Supreme Court has noted that, even in the absence of a direct conflict, a state law violates the supremacy clause when it 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" Id. at 186-87 (quoting Mass. Med. Soc'y v. Dukakis, 815 F.2d 790, 791 (1st Cir. 1987) (citations omitted)).

1. Presumption Against Preemption

Defendants vigorously contend that there should be no

presumption against preemption in this context, for "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,' . . . such as to warrant a presumption against finding federal preemption of a state-law cause of action." Buckman, 531 U.S. at 347 (quoting Rice v. Sante Fe Elevator Corp., 331 U.S. 218, 230 (1947)) (holding that state claims for fraudulent submissions to the FDA were preempted).

The Courts have long presumed that the historic police powers of the states were not to be pre-empted by a federal statute unless that was "the clear and manifest purpose of Congress." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (citations omitted). The Supreme Court has established three primary lines of doctrine on the question of the presumption against preemption. First, as the Defendants state, "fraud on the agency" claims are generally not entitled to a presumption against preemption, for "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." Buckman, 531 U.S. at 347. See also Nathan Kimmel, Inc. v. DowElanco, 275 F.3d 1199, 1205 (9th Cir. 2002) ("Because Kimmel's state law claim hinges upon its contention that DowElanco committed fraud against the EPA - which is hardly 'a field which the States have

traditionally occupied' - we undertake our analysis in this case free from any presumption against preemption.") (quoting Buckman, 531 U.S. at 347).

Second, "[w]hen Congress legislates in a field which the States have traditionally occupied, like medical fee regulation, 'courts must presume that Congress has not preempted state power to act unless that was Congress's "clear and manifest purpose."'" Pharm. I, 263 F. Supp. 2d at 187 (quoting Mass. Med. Soc'y, 815 F.2d at 791 (citation omitted)). See also Medtronic, 518 U.S. at 485 (discussing the presumption against preemption in situations implicating "federalism concerns and the historic primacy of state regulation of matters of health and safety").

Third, the presumption against federal preemption of a state statute designed to foster public health has special force when it appears that the two governments are pursuing "common purposes." Walsh, 123 S.Ct. at 1869 (citations omitted). The "strong medicine" of federal preemption "is 'not casually to be dispensed . . . especially . . . when the federal statute creates a program, such as Medicaid, that utilizes "cooperative federalism"'": 'Where coordinated state and federal efforts exist within a complementary administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one.'" Pharm. Research & Mfrs. of Am. v. Concannon, 249 F.3d 66, 75 (1st Cir. 2001) (quoting Wash.,

Dep't of Soc. & Health Servs. v. Bowen, 815 F.2d 549, 557 (9th Cir. 1987) (quoting N.Y. Dep't of Soc. Servs. v. Dublino, 413 U.S. 405, 421 (1973))), *judgment aff'd sub nom*, 538 U.S. 644 (2003). See also Wis. Dep't of Health & Family Servs. v. Blumer, 534 U.S. 473, 496 (2002) ("Medicaid . . . is designed to advance cooperative federalism When interpreting other statutes so structured, we have not been reluctant to leave a range of permissible choices to the States, at least where the superintending federal agency has concluded that such latitude is consistent with the statute's aims.").

Under this caselaw, the presumption against federal preemption applies to state fraud statutes that are used to reduce the inflated drug costs to the state Medicaid program produced by fraudulent reporting of Best Price information. Medicaid is the paradigmatic program of cooperative federalism, and the federal and state governments share the common goal of reducing drug costs. Concannon, 249 F.3d at 76-77. Further, matters of public health and medical fee regulation have been a field traditionally occupied by the states, and states have historically played a significant role in investigating and prosecuting Medicaid fraud.

Defendants argue that the Rebate Statute and rebate agreements provide HHS, not the states, with the powers to conduct surveys and audits to verify Best Prices and to punish

manufacturers who submit false information to HHS. Defendants argue that this express federal control precludes the traditional presumption against preemption.

There is some strength to this argument, especially in light of the Secretary's decision to keep the pricing information confidential from the states.³ However, upon close scrutiny of the statutory scheme, I conclude that Buckman does not control for two reasons.

First, the Secretary does not make an independent determination with respect to Best Price, but merely acts as a go-between. In contrast, in Buckman, the Food and Drug Administration was "charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals," a task that would be disrupted by state suits. 531 U.S. at 349-350. The Best Price program is one employing cooperative federalism, and so there is no "uniquely federal" interest. Boyle, 487 U.S. at 505.

Second, in Buckman, Congress provided expressly that it was the federal government, not private litigants, that was authorized to file suit for non-compliance, whereas here the

³ States are still able to reverse-calculate the price information, as discussed *infra*. The Court takes no position on the lawfulness of the Secretary's sharing information with states, or any future discovery disputes.

statute provides that the federal remedies are "in addition to other penalties as may be prescribed by law." § 1396r-8(b)(3)(c)(ii).

As a practical matter, the confidentiality of the pricing information and the lack of audit powers inhibits the ability of the states to monitor drug fraud, but those who blow whistles can just as easily blow them into the states' ears. Because the presumption against preemption prevails, the Court concludes that the Defendants must show a "clear and manifest purpose of Congress" to preempt the States' claims.

2. No Actual Conflict

Because the presumption against preemption applies, Defendants must show that there manifestly and clearly is an "actual conflict" between the state claims and the federal statute, Concannon, 249 F.3d at 76, and that any impediment is "severe," not merely "modest," Walsh, 123 S.Ct. at 1868, 1870.

Defendant argues that allowing the States to proceed will "disrupt [the] balance of interests" made by the federal agency or statute. Int'l Paper v. Ouellette, 479 U.S. 481, 496 (1987) (holding that state claims would disrupt balances struck by EPA among public and industrial uses, among states, and between pollution control and cost). See also Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 374-386 (2000) (holding that while state shared federal goal of sanctioning foreign nation, state

remedies disrupted President's flexibility in foreign affairs, for "[c]onflict is imminent when two separate remedies are brought to bear on the same activity" (citations omitted); Buckman, 531 U.S. at 349-51 (holding that state law claims for fraud on the FDA would interfere with FDA's ability to balance safety concerns with need to bring products to market rapidly, for "flexibility is a critical component of the statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives").

Emphasizing that the state law claims depend entirely on obligations that flow from contracts with the federal government, that federal law defines "Best Price," and that HHS establishes the rebates, Defendants argue that the administrative burden on manufacturers and HHS would be onerous if the term "Best Price" had fifty different meanings.

The Secretary denies that the administrative burden would be heavy, for it can simply adjust its formulae by the state. Moreover, as a practical matter, neither the state nor the federal sovereign acts in a vacuum. Massachusetts has described a variety of federal-state law enforcement actions, and the Secretary points out that it would seek the participation of the states in any litigation. The United States considers the Best Prices statute to be one of cooperative federalism, and does not seek the right to exclusive rebate enforcement power. Therefore,

there is no "uniquely federal" interest, and there is no "delicate balance of objectives" to be upset. Any suggestion that allowing states to bring suits to stop Best Price fraud would likely cause manufacturers to change their decisions to participate in the Medicaid program, implicating Buckman-style concerns, would be unrealistic in light of the fact that ten percent of prescriptions are made through the Medicaid program.

Finally, as this Court noted in a prior opinion, state courts are completely competent to interpret terms in federal statutes, particularly with the guidance of HHS. See Pharm. I, 263 F. Supp. 2d at 188-89. Even if state courts came up with varying definitions, at worst, manufacturers would simply have to make accounting adjustments to report and file state-specific Best Price reports, which is overall not a heavy burden. While the state law fraud claims may pose some impediments to a nationwide drug program, these obstacles are not significant.

Protesting that no state has pursued state fraud claims in the fourteen years since the enactment of the Best Prices statute, Defendants accuse the Secretary of being a Tommy-come-lately. In their view, until recently, the Secretary did not think that the States could enforce "Best Price" obligations. Several program releases from the Secretary from 1995 and 1998, and the Best Practices Guide for Dispute Resolution from 1999, mention several times that manufacturers may not dispute the

rebate formulae with the states, but rather "disputes must be based on utilization data."

Defendants place too much weight on these documents that do not discuss states bringing suits, and seem to deal with accounting matters (number of units, late payments, etc.) rather than the definition of "Best Price." One release does discuss the permissible bases for disagreement with calculations, stating that manufacturers may challenge only the utilization data and not the rebate amounts. However, in context this release deals with *manufacturers'* rights, not states', and expressly disclaims being comprehensive.

Finally, the Secretary's interpretation is entitled to judicial deference. The Court asked the agency for its views, and it is not a party with a stake in the litigation. "An agency's interpretation may merit some deference whatever its form, given the 'specialized experience and broader investigations and information' available to the agency." Matz v. Household Int'l Tax Reduction Investment Plan, 265 F.3d 572, 574 (7th Cir. 2001) (quoting United States v. Mead, 533 U.S. 218, 121 S.Ct. 2164, 2175-76 (2001)). The agency's positions in its brief are well-reasoned, and the Court considers its "specialized experience" particularly valuable in determining the extent to which it would be burdened by states' claims. See Walsh, 123 S.Ct. at 1872 (Breyer, J., concurring in part) ("And the law

grants significant weight to any legal conclusion by the Secretary as to whether a program such as Maine's is consistent with Medicaid's objectives.").

The Defendants have failed to show a "clear and manifest purpose" of Congress to preempt the state claims and so have not overcome the presumption against preemption.

B. Montana False Claims Act⁴

Montana seeks relief under its False Claims Act, Mont. Code Ann. § 17-8-231 (West 2003), for both Best Prices fraud and AWP fraud. Defendants have moved to dismiss that portion of the

⁴ Montana's complaint names the following as Defendants: Abbott Laboratories ("Abbott"); Amgen Inc. ("Amgen"); Zeneca, Inc., AstraZeneca US, and AstraZeneca Pharmaceuticals L.P. (collectively, "AstraZeneca"); Aventis Pharmaceuticals, Inc., Aventis Behring L.L.C., and Hoechst Marion Roussel, Inc. (collectively, "Aventis Group"); Baxter International and Baxter Healthcare Corporation (collectively, "Baxter"); Bayer Corporation ("Bayer"); Boehringer Ingelheim Corp., Ben Venue Laboratories Inc., and Bedford Laboratories (collectively, "Boehringer Group"); B. Braun of America, Inc. (collectively with McGaw, Inc. and B. Braun McGaw, "Braun"); Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp., and Apothecon, Inc. (collectively, "BMS Group"); Dey, Inc. ("Dey"); Fujisawa Healthcare, Inc. and Fujisawa USA, Inc. (collectively, "Fujisawa Group"); GlaxoSmithKline, P.L.C., SmithKline Beecham Corporation, and GlaxoWellcome, Inc. (collectively, "GSK Group"); Immunex Corporation ("Immunex"); Johnson & Johnson, Centocor, Inc., Janssen Pharmaceutica Products, L.P., McNeil-PPC, Inc., and Ortho Biotech (collectively, "Johnson & Johnson Group"); Novartis Pharmaceuticals Corporation ("Novartis"); Pfizer, Inc. ("Pfizer"); Pharmacia Corporation and Pharmacia & Upjohn, Inc. (collectively, "Pharmacia Group"); Schering-Plough Corporation and Warrick Pharmaceuticals Corporation (collectively, "Schering-Plough Group"); Sicor, Inc. and Gensia, Inc. (collectively, "Sicor Group"); TAP Pharmaceutical Products, Inc. ("TAP"); and Watson Pharmaceuticals, Inc. ("Watson").

count that pertains to Best Prices fraud, arguing (1) no "claim" was presented; and (2) even if it were, it was not presented to "any state agency or its contractors."

Montana's False Claims Act, enacted in 1981, provides:

A person who knowingly presents or causes to be presented a false, fictitious, or fraudulent claim for allowance or payment to any state agency or its contractors forfeits the claim, including any portion that may be legitimate, and in addition is subject to a penalty of not to exceed \$2,000 plus double the damages sustained by the state as a result of the false claim, including all legal costs.

Mont. Code Ann. § 17-8-231. The parties agree that there are no reported cases under this statute. Montana urges the Court to look to cases construing the federal False Claims Act, 31 U.S.C. § 3729, whereas the Defendants urge the Court to look only to the terms of the statute.

The definition of "claim" is similar in the Montana statute and the federal statute. However, there is a key difference between the federal and the Montana versions. The federal False Claims Act was amended in 1986 to provide coverage for "reverse false claims," that is, claims that lead to an underpayment to the government. See United States v. Am. Heart Research Found., Inc., 996 F.2d 7, 9 (1st Cir. 1993) ("In 1986, the statute was amended . . . to apply to one who knowingly uses 'a false record or statement' in order to 'conceal, avoid, or decrease an obligation to pay . . . money . . . to the Government.'") (quoting 31 U.S.C. § 3729(a)(7)). The language of the statute

prior to the amendment was similar to that in the Montana statute: "anyone who (1) knowingly presents to the [United States] Government . . . a false or fraudulent claim for payment or approval; or (2) knowingly makes . . . a false record or statement to get a false claim paid or approved." Id. (quoting 31 U.S.C. § 3729(a)(1),(2)).

In American Heart, the First Circuit examined the language of the pre-1986 federal statute and several conflicting Supreme Court decisions to find that a "claim" under that version of the statute meant a demand for money or property, so that the statute did not include "reverse false claims." Id. at 10 (finding that fraudulent applications for charity status made to the Postal Service did not constitute "claims" within the meaning of the pre-1986 act despite the fact that the claims led to the underpayment of the Postal Service). See also Rabushka ex rel. United States v. Crane Co., 122 F.3d 559, 565 n.8 (8th Cir. 1997) (noting that every circuit considering whether reverse false claims could be sustained under the pre-1986 act rejected that proposition); United States v. Howell, 318 F.2d 162, 165-66 (9th Cir. 1963) (holding that apparel cleaners' submission of false statements of their receipts, a percentage of which were to be paid to the United States, did not constitute "false claims" within the meaning of the federal False Claims Act). But see United States v. Douglas, 626 F. Supp. 621, 628-29 (E.D. Va.

1985) (examining relevant Supreme Court cases and finding that pre-1986 act encompassed reverse false claims). The First Circuit emphasized in American Heart the importance of being faithful to the language of the statute:

No doubt the effect of fraud on the government is pretty much the same whether too much is extracted from the federal treasury or too little paid in But it is one thing to construe ambiguous language broadly in accord with a remedial purpose; it is quite another matter to stretch language beyond "normal usage or understanding," [United States v. McNinch, 356 U.S. 595, 598 (1958)], when the natural reading matches the very problem that concerned Congress at the time the statute was enacted. When the Supreme Court has thrice affirmed that natural reading and emphasized that a "claim" in this context refers to one for money or property, we think all doubts vanish as to the course this court should follow.

Am. Heart, 996 F.2d at 10.

Defendants first argue that the language of the Montana statute leaves no room for reverse false claims, as it specifies that it covers claims "for allowance or payment," similar to the pre-1986 federal FCA, which covered claims "for payment or approval." Plaintiffs respond by noting that the Montana statute does not define "claim," and by citing cases under the post-1986 federal FCA that permit reverse false claims.

The Court is bound by the language of the Montana statute, which leaves no room for reverse false claims. The claims must be "for allowance or payment to any state agency or contractor," whereas here the statements made by the Defendants to the Secretary under the Best Prices program were intended to, and had

the effect of, reducing their obligations to pay the State. Montana's reading stretches the statute beyond its normal usage and understanding.

The Montana False Claims Act count as it relates to the Best Prices claim is therefore dismissed.

C. Montana and Nevada Medicaid Fraud Statutes

1. Montana

In Count III, Montana brings AWP and Best Prices claims under the Montana Medicaid Fraud Statute, Mont. Code Ann. § 53-6-160, (West 2003) and § 53-6-143(4) (West 2003). Section 160 states:

(1) A person who submits to a medicaid agency an application, claim, report, document, or other information that is or may be used to determine eligibility for medicaid benefits, eligibility to participate as a provider, or the right to or amount of payment under the medicaid program is considered to represent to the department, to the best of the person's knowledge and belief, that the item is genuine and that its contents, including all statements, claims, and representations contained in the document, are true, complete, accurate, and not misleading.

The Montana Code dictates the principles of statutory interpretation. In construing Montana statutes, "[w]ords and phrases used . . . are construed according to the context and the approved usage of the language." Mont. Code Ann. § 1-2-106 (West 2003). Statutes are to be "liberally construed with a view to effect their objects and to promote justice." Mont. Code Ann. § 1-2-103 (West 2003). "A statute must be construed reasonably and

in a way that is best able to effectuate its purpose, rather than in a way that would weaken that purpose." Baitis v. Dep't of Revenue of Mont., 319 Mont. 292, 300, 83 P.3d 1278, 1283 (2004). These principles apply to the Medicaid statute, pursuant to which "[t]he function of the court . . . is to interpret the intention of the statute . . . from the plain meaning of the words, and if the meaning of the statute . . . can be determined from the language used, the court is not at liberty to add or to detract from the language therein." Glendive Med. Ctr., Inc. v. Mont. Dep't of Public Health and Human Servs., 310 Mont. 156, 160, 49 P.3d 560, 563 (2002). "Additionally, absent ambiguity in the language of the statute or rule, [the court] may not consider legislative history or any other means of statutory construction." Id.

Defendants' principal argument is that any allegedly false information is sent to the Secretary of HHS, not to Montana's "Medicaid agency," and so Montana's Medicaid Fraud Statute does not apply. "Medicaid agency" is defined by statute to mean: "any agency or entity of state, county, or local government that administers any part of the medicaid program, whether under direct statutory authority or under contract with an authorized agency of the state or federal government." Mont. Code Ann. § 53-6-155(9) (West 2003).

Under § 53-6-160(4), Plaintiffs argue that Defendants are

liable even if they did not make a false statement themselves to the state "medicaid agency," so long as a direct or indirect result of their conduct was a false statement being made to the state medicaid agency. Section 53-6-160(4) provides that "[a] person is considered to have made or to have authorized to be made a claim, statement, or representation if the person had the authority or responsibility to make the claim, statement or representation . . . and exercised or failed to exercise that authority or responsibility and, as a direct or indirect result, the false statement was made."

The parties agree that the Secretary sends to states URA's, calculated according to the formulae in the Statute and the rebate agreements using the pricing information provided by the Defendants. According to the Secretary's Brief and the Model Rebate Agreement, the states then invoice the manufacturers. If the Best Prices or the AMP's that the Defendants reported were false, then the URA's, which represent the products of calculations performed on AMP's and Best Prices and so which were the Defendants' responsibility, were also false. These URA's would "be [documents or information] used to determine . . . the amount of payment under the medicaid program," assuming that the States invoiced the Defendants on the basis of the URA's and the

Defendants paid based on the invoices.⁵

Plaintiffs seem to contend alternatively, although the argument is vaguely formed, that the rebate checks, paid directly to the states, are the false information submitted to "a Medicaid agency" within the meaning of the statute. Plaintiffs argue that the rebate checks based on fraudulent prices increase the net cost of the drugs. However, a rebate check is not a document that "is or may be used to determine . . . the right to or amount of payment under the medicaid program." Rather, the check is the payment itself. Moreover, Montana does not use Best Price data or rebate amounts to determine the right to or the amount of payment to Montana providers. Rather, Montana reimburses most providers for prescription drugs at AWP-15% and uses the rebates to reduce the net cost of drug reimbursements to the State. As Defendants fairly discern, Plaintiffs conflate the "cost to" the Montana Medicaid program with the "payment by" the program.

Accordingly, inferring that the Defendants cause the Secretary to make false statements to the states regarding URA's which are used to invoice the manufacturers, the Court denies the motion to dismiss that portion of the Medicaid claim pertaining to Best Prices. Defendants have not moved to dismiss the

⁵ The Court notes that in general the briefing on the state claim issues was scant and poorly-developed. Much of the information concerning the sequence of documents required for rebate payments was gleamed from the Secretary's brief.

Medicaid fraud claim for failure to state a claim under § 53-6-160 with respect to alleged fraudulently inflated AWP's. Cf. United States v. Parke-Davis, 147 F. Supp. 2d 39, 52-53 (D. Mass. 2001) (discussing causation under the False Claims Act). That latter claim survives as well.

2. Nevada⁶

Nevada's Medicaid Fraud Statute, Nev. Revised Stat. Ann. § 422.540 (West 2003), provides:

1. A person, with the intent to defraud, commits an offense if with respect to the plan he:
 - (a) Makes a claim or causes it to be made, knowing the claim to be false, in whole or in part, by commission or omission;
 - (b) Makes a statement or representation for use in obtaining or seeking to obtain authorization to provide specific goods or services, knowing the statement or representation to be false, in whole or in part, by commission or omission;
 - (c) Makes or causes to be made a statement or representation for use by another in obtaining goods or services pursuant to the plan, knowing the statement or representation to be false, in whole or in part, by commission or omission; or
 - (d) Makes or causes to be made a statement or representation for use in qualifying as a provider, knowing the statement or representation to be false, in whole or in part, by commission or omission.

"Claim" is defined as "a communication, whether oral, written, electronic or magnetic, which is used to identify specific goods, items or services as reimbursable pursuant to the plan, or which

⁶ Nevada's Amended Complaint names the following as Defendants: Amgen; AstraZeneca; the Aventis Group; the Boehringer Group; Braun; the Fujisawa Group; Immunex; the Johnson & Johnson Group; Novartis; Pfizer; the Schering-Plough Group; the Sicor Group; and Watson.

states income or expense and is or may be used to determine a rate of payment pursuant to the plan." Nev. Rev. Stat. Ann. § 422.470 (West 2003). "'Plan' means the state plan for Medicaid established pursuant to NRS 422.271." Nev. Rev. Stat. Ann. § 422.480 (West 2003).

In interpreting its Medicaid statute, the Nevada Supreme Court has said:

It is well established that when the language of a statute is plain and unambiguous, a court should give that language its ordinary meaning and not go beyond it. However, if a statute is susceptible to more than one natural or honest interpretation, it is ambiguous, and the plain meaning rule has no application. When a statute is ambiguous, the legislature's intent is the controlling factor in statutory interpretation.

Nevada Dep't of Human Resources, Welfare Division v. Ullmer, 87 P.3d 1045, 2004 WL 637782, *pinpoint citations unavailable*, (Nev. April 1, 2004) (internal quotation marks and citations omitted) (balancing government's legitimate Medicaid interest in recovering benefits from deceased recipient's estate with policy of avoiding spousal impoverishment in interpreting Medicaid statute). When a statute is ambiguous, courts must construe it "according to that which reason and public policy would indicate the legislature intended." Id. A court should "infer legislative intent by reading a particular statutory provision in the context of the entire statutory scheme." Nylund v. Carson City, 117 Nev. 913, 916, 34 P.3d 578, 580-81 (2001) (citations omitted).

Defendants make three arguments in support of their motion to dismiss this claim. First, Defendants again argue that the claim fails because their allegedly false statements were made to the Secretary, not Nevada. However, the Nevada statute provides broader coverage for one who "makes or causes to be made" a statement or communication without specifying to whom the statement must be made, so long as it is "with respect to the plan." This language is sufficiently elastic to encompass the statements made by Defendants to the Secretary relating to rebates owed to the Nevada Medicaid plan. Additionally, the Secretary's statements regarding URA's sent to the states constitute statements caused to be made.

Second, Defendants argue that pharmaceutical manufacturers are not providers. However, Nevada precludes fraud by "persons," not just providers.

Third, Defendants argue that the term "claim" under the Nevada statute does not encompass either the checks themselves or the statements made to the Secretary because the statements to the Secretary and the checks do not "identify specific goods . . . as reimburseable pursuant to the plan," and are not a communication that states "income or expense and is or may be used to determine a rate of payment pursuant to the plan."

This argument with regards to the checks is persuasive because Nevada reimburses most drugs under a formula 10 percent

of AWP plus a dispersing fee. Again, the fact that the rebates may affect the net cost of the drugs does not affect the initial "rate of payment" for the drugs.

However, the statements made by the Defendants to the Secretary which result in the transmission of false URA's to the State constitute communications that identify the expenses of drugs that will determine the "rate of payment pursuant to the plan" required to be made by the Defendants. Again, the record regarding the role of URA's is not well developed, and will need fuller development at the summary judgment stage.

Finally, Plaintiffs also rely on the general prohibitions against submitting false statements or representations contained in Nev. Revised Stat. Ann. § 422.540 (1)(b)-(d). The alleged false statements made quarterly to the Secretary under the Best Price statute are made in order to obtain continued authorization to provide drugs under the state plan, since a failure to report Best Prices results in exclusion from the program. The statements made to the Secretary therefore fall within Nev. Rev. Stat. Ann. § 422.540(1)(b). See generally 42 U.S.C. §1396r-8(a)(1) (requiring a drug manufacturer to enter into a rebate agreement with the Secretary in order for matching funds to be made available for that manufacturer's covered outpatient drugs).

D. Government Knowledge Under Deceptive Trade Practice Statutes

The Defendants have moved to dismiss Count II of the Montana Second Amended Complaint, claiming deceptive trade practices in violation of Mont. Code Ann. §§ 30-14-101 - 1414 (West 2003). The Complaint seeks restitution for losses suffered by the State of Montana as a result of the AWP inflation scheme and the Best Price scheme, civil penalties for Defendants' conduct, and injunctive relief. The Defendants also move to dismiss a similar AWP claim under Count III of the Nevada Complaint, which claims deceptive trade practices on behalf of Nevada in violation of Nev. Rev. Stat. Ann. §§ 598.0903 - 598.990 (West 2003).

Defendants contend that as a matter of law the States knew of the Defendants' misconduct and therefore cannot bring charges of fraud.⁷ Defendants point to numerous portions of the Complaints and public records that they claim show that the States were on inquiry notice of the fraud claims, because they were aware of the existence of a spread.⁸ Defendant Abbott Laboratories also argues that the States knew the upper limit on the AMP of a drug from the Best Price rebates, for they could

⁷ The Defendants have not moved to dismiss the claims brought in *parens patriae* capacities under these statutes on this ground in their consolidated motion. The Montana Complaint (Count I) and the Nevada Complaint (Count I) seek restitution for losses incurred by Montana and Nevada residents as a result of the AWP inflation scheme.

⁸ Defendant B. Braun also moves to dismiss on the ground that the States' knowledge started the running of the applicable statutes of limitations.

divide the rebate payment by .11 or .151, depending on the category of the drug, to derive the AMP or its upper limit. The States would then know that the AWP was substantially higher than the AMP, putting them on notice of the spread.

The States respond that the statutes do not require the States to be deceived, that they had no notice of the extent of the spread, and that the knowledge of state officials should not be imputed to claims made in a *parens patriae* capacity on behalf of state residents. Finally, they assert that these arguments present issues to be presented to a fact-finder, not to be decided at the motion to dismiss phase.

When all reasonable inferences are drawn in favor of Plaintiffs, Defendants have not shown that the States can prove no set of facts that would entitle them to relief, particularly with respect to the *parens patriae* claims. With a fuller record, including many of the documents cited by Defendants, the Court will revisit the issue at summary judgment.

E. Nevada RICO Claims

In Count IV of its Complaint, Nevada brings claims for civil damages under its RICO statute, Nev. Rev. Stat. Ann. § 207.400 (West 2003). Nevada pleads "association in fact" "Defendant-Publisher" enterprises of the kind dismissed in this Court's prior opinion, Pharm. III, 307 F. Supp. 2d at 203-05. Briefing on this issue was completed before the Court published that

decision.

Defendants move to dismiss on two grounds: (1) Nevada has failed to plead "enterprises"; and (2) Nevada lacks standing to sue under its own statute.

Nevada's statute provides, in relevant part:

It is unlawful for a person:

- . . .
- (c) Who is employed by or associated with any enterprise to conduct or participate, directly or indirectly, in:
- (1) The affairs of the enterprise through racketeering activity; or
 - (2) Racketeering activity through the affairs of the enterprise.

Nev. Rev. Stat. Ann. § 207.400. The statute also states:

Enterprise includes:

1. Any natural person, sole proprietorship, partnership, corporation, business trust or other legal entity; and
2. Any union, association or other group of persons associated in fact although not a legal entity.

Nev. Rev. Stat. Ann. § 207.380.

Nevada's anti-racketeering statutes are patterned after the federal RICO statutes. See Siragusa v. Brown, 114 Nev. 1384, 1398, 971 P.2d 801, 810 (1999) (quoting Hale v. Burkhardt, 104 Nev. 632, 634-35, 764 P.2d 866, 867-68 (1988)). Where the Nevada legislature intends to imitate particularly meaningful language in the federal RICO statute, it expressly adopts the language of the federal statute. Id. at 811, n.15.

Nevada pleads the same form of "association in fact" publisher enterprise as did the plaintiffs in the Amended Master

Consolidated Complaint. The federal and state statutes are almost identical on the key point: Nevada's statute provides for a "group of persons associated in fact," whereas federal RICO provides for a "group of individuals associated in fact." Nevada has not attempted to distinguish the federal statute on any basis, and neither party has cited Nevada caselaw. Therefore, Nevada's state RICO claim is dismissed for failure to plead an enterprise. I do not reach the standing issue.

F. Rule 9(b)

1. AWP Claims

The Court has discussed Fed. R. Civ. P. 9(b) at length in its prior opinions. See Pharm. III, 307 F. Supp. 2d at 208-10; Pharm. I., 263 F. Supp. 2d at 194. Plaintiffs have amended their Complaints consistent with these opinions to state the specific drug sold by each Defendant and its alleged fraudulent AWP. The States need not identify specific purchasers of the drugs to recover as *parens patriae*, so long as they allege that the drugs with the allegedly fraudulent AWP's have been purchased by their residents. Therefore, the motion to dismiss on these grounds is **DENIED**.

2. Best Price Claims

Defendants argue that the Best Price claims fail under Fed. R. Civ. P. 9(b). Nevada alleges only two specific examples, referring to AstraZeneca's product, Zoladex, and Pfizer's

product, Lipitor. (¶¶ 398-403.) The claims against the other companies are dismissed under Fed. R. Civ. P. 9(b). Montana alleges these two examples and four others: GSK Group's Flonase and Paxil, and Bayer's Cipro and Adalat CC. Montana's claims against companies other than AstraZeneca, Pfizer, GSK Group and Bayer are also dismissed under Fed. R. Civ. P. 9(b).

G. Miscellaneous

1. B. Braun of America, Inc. (BBA) argues that the claims against it must be dismissed for improper service because copies of the amended complaints and summonses were sent only via mail to BBA's chief executive officer. Service must be valid under the law of the transferor states, here, Nevada and Montana. See In re Lib. Eds. of Children's Books, 299 F. Supp. 1139, 1142 (J.P.M.L. 1969); In re Ski Train Fire in Kaprun, Austria on Nov. 11, 2000, 230 F. Supp. 2d 392, 399 (S.D.N.Y. 2002); Charles A. Wright, *et al.*, 15 Fed. Prac. & Proc. Juris. 2d § 3865 (2003). Montana seems to allow service by mail with some conditions, see Mont. R. Civ. P. 4(D)(b)(i), but Nevada does not, see Nev. R. Civ. P. 4(d)(2). Plaintiffs argue incorrectly that Massachusetts law applies, and do not discuss the relevant Montana and Nevada laws. As Plaintiffs have not disputed that service was made only by mail, Nevada's Complaint against B. Braun is dismissed. B. Braun's motion to dismiss Montana's Complaint for want of service is denied. Discovery shall proceed with respect to B. Braun, and

Montana shall respond to the issues of personal jurisdiction and whether the named entity is a proper Defendant for the drugs listed by August 24, 2004.

2. TAP has moved to dismiss for lack of service. Plaintiffs state that counsel for TAP agreed to accept service of process, as mentioned in footnote 24 to the States' Surreply. However, there is no evidence of service. The Plaintiff's claims against TAP are dismissed without prejudice.

3. The Court has addressed the issues of Boehringer Ingelheim and Amgen separately.

4. The States agree that they cannot, and do not, assert a Best Price claim for non-innovator, multiple source drugs that are rebated at AMP less 11 percent.

5. The Court dismisses all fraud claims concerning drugs covered by the 2001 and 2003 settlements between Montana and Bayer, even those brought in a *parens patriae* capacity.

6. The Defendants make other arguments which were either addressed in other opinions or lack merit.

ORDER

Nevada's state RICO claim (Count IV) is dismissed. Montana's False Claims Act "Best Price" claims (Count IV) are dismissed. Montana's Medicaid Fraud Act (Count III) "Best Price" claims are dismissed against all Defendants and with respect to all drugs except GSK Group's Flonase and Paxil, Bayer's Cipro and

Adalat CC, AstraZeneca's Zoladex, and Pfizer's Lipitor. Nevada's "Best Price" Medicaid claims (Count V) are dismissed against all Defendants and with respect to all drugs except AstraZeneca's Zoladex and Pfizer's Lipitor. The Court dismisses the claims against TAP without prejudice and Montana's claims against Bayer covered by the settlement with prejudice.

PATTI B. SARIS
United States District Judge